108 Improving Tissue Traceability by Internationally Standardized Coding

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This session will offer background information on the Sixty-Third World Health Assembly resolution concerning human organ and tissue transplantation (Resolution WHA63.22). The resolution urges member states to move forward on a variety of actions to improve the safety and availability of organs and tissues. Recommendations included encouraging the implementation of globally consistent coding systems for human cells, tissues and organs to facilitate national and international traceability of materials for transplantation. The presentation will then move on to describe the use of ISBT 128, already well established as a standard for blood transfusion, for the coding and labeling of tissues, cells and organs. It will describe the current status of development and identify the benefits to the hospital of a single coding system for all biologics.

- Upon completion of this course, the participants will be able to identify the shortcomings of current traceability systems
- Identify requirements for an acceptable global traceability system
- List actions, including the implementation of ISBT 128, that may be taken to improve tissue traceability

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Improving Tissue Traceability through an Internationally Standardized Coding System

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Learning Objectives

- By completion of this course, participant will be able to
  - Identify the shortcomings of current traceability systems
  - Identify requirements for an acceptable global traceability system
  - List actions, including the implementation of ISBT 128, that may be taken to improve tissue traceability

Agenda

- Current status of Traceability
- Unique (Distinct) Identification
- Current Regulation
- Weaknesses of Existing Systems
- Time
- Tools for Improvement
- International Perspective
- ISBT 128 Solutions
- How you can help

Traceability

- Effective tracking from donor to recipient and *vice versa*
- Needed to support
  - Product recall
  - Biovigilance
  - Patient safety
- Regulatory requirement in many countries

Traceability Requirements

- Traceability must deliver a trail from:
  - recipient to donor
  - donor to all other recipients
  - donor to all unused biologics
- Must include all biologics from the donor regardless of recovery agency or processor
- Must be timely
- Must operate in the international context

Traceability in Transfusion

- Well established in blood transfusion
- Supported by:
  - Unique identification (ISBT 128 or national)
  - Extensive use of bar coding
  - Standardized coding system (ISBT 128)
  - Computerized hospital blood bank systems
- Timeliness? Audit?

Traceability in Tissue Transplant

- Lack of unique identification
- Not all critical information is bar coded
- If bar codes exist on product labels, they are not standardized (each supplier is different)
- While hospitals may have computerized systems,
  - They may not be able to interpret tissue bar codes
  - High dependence on manual records and transcription
  - Manual systems are neither efficient nor accurate
- Distributed responsibility (OR, blood bank, anatomical pathology, materials management, ...)

Cell and Tissue Banking

- Cell and Tissue Banking Journal
  - Special Edition on Traceability
  - CATB (2010) 11
- Important paper on the analysis of recall events in USA – Brubaker and Wilson

Traceability in Tissue Transplant

"In the USA, lessons can be learned by all from experiences with tissue recall events that have repeatedly shown gaps exist in traceability networks."

S Brubaker, D Wilson 2010

Traceability in Tissue Transplant

"In the USA, lessons can be learned by all from experiences with tissue recall events that have repeatedly shown gaps exist in traceability networks."

S Brubaker, D Wilson 2010

- This conclusion may well be applicable in many other countries

Recall Analysis

- Five recall cases reported (1991-2006)
- Tissue unaccounted for in four cases
- In fifth case full accountability only achieved after FDA intervention
- Unaccounted grafts were between 4.6% and 9% of grafts distributed

The uncomfortable truth

Donated tissue is a gift of enormous value which we have the obligation to treat with care and respect....

The uncomfortable truth

Donated tissue is a gift of enormous value which we have the obligation to treat with care and respect....

BUT

...we lose track of between 5% and 9% of donated tissue and are unable to identify where it went or how it was used.

The Underlying Problems

- Lack of unique identification
- Lack of standardized descriptions and coding
- Manual transcription

Unique (Distinct) Identification

- Unique identification is essential for effective traceability
- Traceability runs from donor to recipient
- Unique identification must run through the entire supply chain from donor to recipient
- Independent assignment of identifiers by tissue banks leads to loss of uniqueness through critical parts of the supply chain

The "Uniqueness Problem" is International

- Nationally unique identification may cease to be unique internationally
- Impacts both imports and exports
- Tissue can travel through multiple regulatory environments
- Traceability boundaries may be unclear

Lack of Unique Identification

- Handling of tissues by multiple departments within a hospital further complicates the process
- Two surgeons could get similar tissue from different suppliers with the same identifier and not know it
  - When blood had non-unique identifiers, it was re-numbered at the hospital
  - Tissues may not be re-numbered at the hospital—even if the hospital was aware of duplicate identifiers

21 CFR 1271.290 Tracking

- *Distinct Identification Code*. As part of your tracking system, you must ensure: That each HCT/P that you manufacture is assigned and labeled with a distinct identification code, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P; and that labeling includes information designed to facilitate effective tracking, using the distinct identification code, from the donor to the recipient and from the recipient to the donor.

Joint Commission Transplant Safety

- The hospital's records allow any tissue to be traced from the donor or tissue supplier to the recipients or other final disposition, including discard, and from the recipients or other final disposition back to the donor or tissue supplier
- The hospital documents in the recipient's medical record the tissue type and its unique identifier

European Directive - Traceability

- Member States shall ensure that all tissues and cells procured, processed, stored or distributed on their territory can be traced from the donor to the recipient and vice versa. This traceability shall also apply to all relevant data relating to products and materials coming into contact with these tissues and cells.

European Directive - Traceability

- Member States shall ensure the implementation of a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

European Directive - Traceability

- Tissue establishments shall keep the data necessary to ensure traceability at all stages. Data required for full traceability shall be kept for a minimum of 30 years after clinical use. Data storage may also be in electronic form.

Lack of Standardized Descriptions and Coding

- A scanned bar code from one supplier doesn't have the same meaning as the same code from a different supplier

Supplier #1: Dowel = 9245

Supplier #2: Femoral Head = 9245

Lack of Standardized Descriptions and Coding

- Similar products from different suppliers have entirely different product codes

Supplier #1 Femoral Head:
Identifier: X1234
Product Code: FEMH

Supplier #2 Femoral Head:
Identifier: 43-354097
Product Code: 8631

Lack of Standardized Descriptions and Coding

- Bar codes not standardized
- Computer systems can't interpret
- Costly customization required to interpret multiple supplier labels

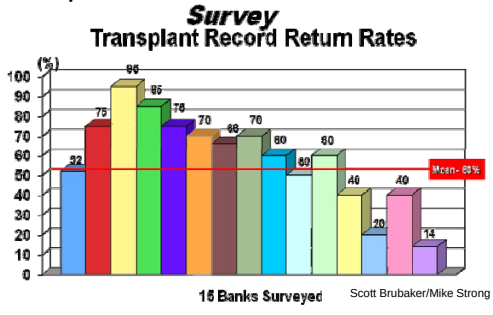
Supplier #1 Femoral Head:
Identifier: X1234
Product Code: FEMH

Supplier #2 Femoral Head:
Identifier: 43-354097
Product Code: 8631

Manual transcription

- Manual tracking of products in many facilities because:
  - Bar codes not standardized
  - Computer systems can't interpret non-standardized codes
  - Costly customization required to interpret multiple supplier labels
- Rely on return of paper "Implant Cards"

Implant Cards - AATB Survey 2006



Scott Brubaker/Mike Strong

These problems are:

- Long standing (over 20 years!)
- Widespread
- Problems are systemic
- Rely on manual transcriptions and written records
- Identifiers are not truly unique
- Information is not standardized
- No change = no improvement

Time is critical

- Once we know that a biologic is unsafe, or possibly unsafe, we have a duty to remove it from the supply chain as rapidly as possible
- Patient safety is compromised whilst known or potentially unsafe product remains in stock
- Little information is available on the recall time line

Traceability Window Period

- The traceability window period is the time
  - from the initial detection of a potential risk associated with a biologic product
  - to the point where all remaining unused implicated product has been removed from the supply chain
- Effective traceability minimizes the traceability window period
- Patients transfused or transplanted during the window period will want to know why!

Traceability Window Period

- How important is this?
  - To the processor?
  - To the clinician?
  - To the patient?
- What is an acceptable window period?

Changing the context:

A Challenge

- 2 working days for tissue distributed within the country
- 5 working days for exported tissue

Tools for improvement

- Globally unique identification of each graft
  - Electronic (bar code) presentation of critical information
- Standardization of information within bar codes
- Increased use of computers in the capture and storage of information
- Audit of traceability effectiveness and recall timeliness

International Perspective

- Strong M, Shinozaki N. Coding and Traceability for Cells Tissues and Organs for Transplantation. Cell and Tissue Banking (2010) 11:305
- Excellent overview of the situation and issues
- Makes five recommendations:

Strong and Shinozaki

- Efforts be made to encourage the introduction of a standardized international coding system for donation identification numbers, such as ISBT 128, for all donated human biologic products
- Focus on global traceability for all donated human biologic products
- Encourage communication between international stakeholders to develop consensus on common grounds

Strong and Shinozaki

- Promote suitable international forums to be established to expand the international terminology for donated human biologic materials
- Any move towards adopting globally unique identification should be compatible with a well established standard coding system so that the progression towards automated data capture and computerized records can be achieved

World Health Assembly

- Growing consensus on the need for international harmonization of coding and labeling of biologics
- World Health Assembly Resolution WHA63.22 (2010)
  - Resolution passed at the 63rd World Health Assembly, Geneva, May 2010
  - "Human Organ and Tissue Transplantation"
  - Applies to 193 member states of the United Nations

WHA63.22

- "Conscious of the extensive cross-boundary circulation of cells and tissues for transplantation..."
- "Urges Member States..."
- "...to encourage the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation."

WHO/ICCBBA Collaboration

- WHO and ICCBBA have developed a joint work program that will focus on:
  - Developing a global standard nomenclature for organs
  - Develop an internationally agreed core nomenclature for human cells, tissues and organs (HCTO) to support the consistent and comparable reporting of donation and transplantation activity worldwide
  - Develop an educational programme to strengthen expertise globally in the need for, and practice of, traceability, vigilance and global standardization

ISBT 128 for Cells and Tissues

- ISBT 128 has been adopted as the global system for coding and labeling of cell therapy products by international professional and accreditation bodies
- ISBT 128 for Tissues exists and is in use in some parts of Europe
- International terminology activity under way for various tissues: ocular, skin, cardio-vascular, and tendons

ISBT 128

- ISBT 128 already used in many hospitals
- Equipment and label vendors already support ISBT 128
- Software enhancements to support tissue can be built upon existing foundation
- Hospital staff are familiar with ISBT 128
- Established and proven management organization

Tools for Improvement: ISBT 128

- Globally unique identification of each graft
- Electronic (bar code) presentation of critical information
- Standardization of information within bar codes
- Increased use of computers in the capture and storage of information
- Audit of traceability effectiveness and recall timeliness

Global Implementation Strategies for Tissues

- UK: Implemented ISBT 128 identifiers first; followed with product codes
- Poland: Implemented ISBT 128 identifiers, national product codes
- Denmark: Implemented both identifiers and product codes at the same time—but not in all hospitals/tissue processors

ISBT 128 for Tissues in North America

- American Association of Tissue Banks (ATBB) 2010 five-year strategic plan states AATB will "Participate in and support ISBT 128 coding for tissue labeling"
- AATB and ICCBBA created a joint advisory group
- Developed an interim implementation guidance document

Implementation Guidance

- Implementation is not easy—flexibility is required
- Minimum compliance standard for tissue banks
- Some of the options allowed:
  - Single or multi-phase implementation
  - Selection of linear or 2-D symbols
  - Size and placement of ISBT 128 information

ISBT 128 Basics

- For a product to be identified uniquely, it must have a unique combination of
  - Donation Identification Number (DIN)
  - Product Code (PC)

DIN: A9999 12 123345
PC: T0001 001

DIN: A9999 12 123345
PC: T0045 005

Same donation number, multiple product codes

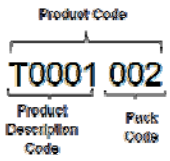
DIN: A9999 12 128897
PC: T0045 005

DIN: A9999 12 123345
PC: T0045 005

Multiple donation numbers, same product codes

ISBT 128 Basics: Product Code

- There are two parts to a product code
  - Product Description Code
  - Pack Code



Single Phase Adoption

- Introduce donation identification numbering
- Use a unique product code for each graft from the donor
- The combination of DIN and product code is globally unique

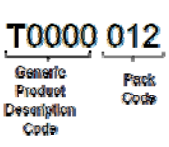
Multi-Phase Adoption

- Introduce donation identification numbering
- Utilize unique product identification without specific product description
  - Uses a generic product description code
  - Assign a unique pack code to each graft from the donor
- The combination of DIN and pack code is globally unique

Generic Product Description/Unique Pack Code

- Text interpretation of T0000 is Donated Human Tissue
- A unique pack code is assigned to each graft from this donation (001 – 999)
- Graft description appears elsewhere on labeling (text only)

This is an interim measure only

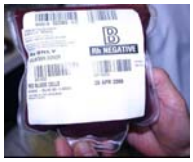


Symbol options

- Linear bar codes (Code 128)
- 2-D bar codes (Data Matrix)

Size and Placement

- ISBT 128 label is the only label for blood and cellular therapy, but it may only be a part of a tissue label
- "ISBT 128" text will appear near ISBT 128 bar codes



ISBT 128 Portion of Label

What Next in North America?

- ISBT 128 adapted for Tissues
- AATB Support
- Guidance documentation
- End user support
  - Tissue suppliers cannot invest in systems for standardized bar codes unless they know their customers want them

Further information

- ICCBBA web site – www.iccbba.org
- ICCBBA help desk – iccbba@iccbba.org